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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/816,248	03/26/2001	Peter Baumann	89491/201	8759

30542 7590 04/19/2002

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EXAMINER
MYERS, CARLA J

ART UNIT	PAPER NUMBER
1634	//

DATE MAILED: 04/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/816,248	BAUMANN ET AL.	
	Examiner	Art Unit	
	Carla Myers	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 26 March 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Applicant's election without traverse of Group I, claims 1-5 in Paper No. 9 is acknowledged.

2. Claims 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 3 is drawn to an isolated naturally occurring variant of a protein having the sequence set forth in SEQ ID NO :13. Claim 4 is further limited to splice variants of the protein having the sequence set forth in SEQ ID NO: 13. The specification teaches 2 splice variants of the human Pot1 protein, wherein said variants consist of SEQ ID NO: 15 and 17. However, the specification does not disclose any additional splice variants and does not disclose any other types of variants of the human Pot1 protein. Accordingly, while varaints of the hPOT1 protein having the amino acid sequence of SEQ ID NO: 15 and 17 meet the written description requirements of 35 U.S.C. 112, first paragraph, the specification does not disclose and fully characterize the genus of any variant os the protein of SEQ ID NO: 13. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed". Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision. In *The Regents of the*

University of California v. Eli Lilly (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...' requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention". In analyzing whether the written description requirement is met for a genus claim, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, only 2 members of the broadly claimed genus of splice variants of the human Pot1 protein have been defined in terms of their structure. The recitation in the claims of a variant of the protein of SEQ ID NO: 13 is so broad as to not provide a meaningful structural limitation to the claims. As broadly defined in the specification, variants include proteins which may comprise any number of additions, deletions or substitutions in the amino acid sequence of SEQ ID NO: 13. The claims do not set forth the identity which might be shared between the variant and SEQ ID NO: 13. Furthermore, the claims do not set forth specific splice sites within SEQ ID NO: 13 which would result in the generation of additional splice variants. It is then determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (e.g., in terms of a

specific functional activity). In the instant case, no such identifying characteristics have been provided for any additional variants. Specifically, the claims do not provide a functional limitation for the claimed proteins. Accordingly, the claims include variants of the protein of SEQ ID NO: 13 which do not have the ability to bind single-stranded telomeric DNA. Yet, the specification has not disclosed any variants having functional properties distinct from the proteins of SEQ ID NO: 13, 15 or 17. The broadest reasonable interpretation of the claims indicates that the claims are inclusive of a large genus of polymorphic variants and splice variants of the hPot1 protein. However, the specification does not exemplify any polymorphisms in the hPot1 protein. While one could contemplate an amino acid substitution, deletion or addition at each and every position in the hPot1 protein, such alterations are not considered to be equivalent to specific naturally occurring allelic variants of the hPot1 protein. Accordingly, knowledge of the sequence of the wild-type hPot1 protein does not allow the skilled artisan to envision all of the contemplated polymorphismic and splice variants encompassed by the claimed genus of proteins. Therefore, Applicants have not provided sufficient evidence that they were in possession, at the time of filing, of the invention as it is broadly claimed and thus the written description requirement has not been satisfied for the claims as they are broadly written. Applicants attention is drawn to the Guidelines for the Examination of Patent Applications under 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

3. Claims 2-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 5 are indefinite over the recitation of "capable of binding" because capability is a latent characteristic and the claims do not set forth the criteria by which to determine capability. That is, it is not clear whether the recited proteins have the potential to bind or do in fact bind to single-stranded telomeric DNA. Amendment of the claim to read e.g. "... wherein the variant binds single-stranded telomeric DNA" would obviate this rejection.

Claims 3 and 4 are indefinite over the recitation of "naturally occurring, variant of a protein having the sequence set forth in SEQ ID NO: 13". Because the claims do not recite any structural limitations for the claimed protein, it is unclear as to whether the claims include proteins comprising SEQ ID NO: 13 or if the claims include only proteins which have a sequence that is distinct, in some unstated manner, from the protein of SEQ ID NO: 13.

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Isogai (Accession No. BAA91568, February 22, 2000).

Isogai et al disclose a protein having an amino acid sequence identical to the protein of SEQ ID NO: 13. The protein of Isogai also comprises an amino acid sequence identical to instant SEQ ID NO: 5 (see amino acids 1-109 of the protein of Isogai). The protein of Isogai comprises an amino acid sequence having at least 93% identity with SEQ ID NO: 15 and having at least 96% identity with SEQ ID NO: 17. With respect to claims 3 and 4, since the claims do not recite any particular structural limitations for the claimed proteins, the claims are considered to be inclusive of the protein of Isogai.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. The fax number for the Technology Center is (703)-305-3014 or (703)-305-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to Chantae Dessau whose telephone number is (703) 605-1237.

Carla Myers

April 15, 2002

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER